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EXAMINER				
NAGPAUL, JYOTI				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

09/841,363

Applicant(s)

LABUDA ET AL.

Examiner

JYOTI NAGPAUL

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date: \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Amendment filed on February 15, 2010 has been acknowledged. Claims 1-38 are pending.

#### ***Response to Amendment***

Rejection of Claims 1-10, 13-15, and 17-37 as being unpatentable over Stanley et al ('658) in view of Knodle et al ('720) has been modified in light of applicant's amendments.

Rejection of Claims 11-12 as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Yafuso et al ('172) has been modified in light of applicant's amendments.

Rejection of Claim 16 as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Hauenstein et al ('727) has been modified in light of applicant's amendments.

Rejection of Claim 38 as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Alcala et al has been modified in light of applicants amendments.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's recite "only in a correct orientation" and "only in one orientation". This limitation of "only in a correct or one orientation" is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 1-10, 13-15, and 17-37** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al ('658) in view of Knodle et al ('720).

Stanley et al disclose a transducer for measuring oxygen in an airway breathing tube which comprises, referring to Figure 2, a light source/radiation source (27) oriented to emit at least a wavelength of electromagnetic radiation capable of exciting a luminescable composition of a luminescable element (25) of a respiratory flow component (24). Applicants further recite "a replaceable luminescable element". It is the examiners position that this is inherently taught by Stanley on the basis that any structure can be replaceable. Applicants further recite "which when excited emits at least one wavelength of second electromagnetic radiation." This limitation is considered a process and/or intended use limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Since claim 1 is drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claims, which are considered in determining the patentability of the apparatus itself. This recited process or intended use limitation is accorded no patentable weight to an apparatus. Process limitations are not germane to patentability to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed

invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Stanley teaches a radiation source capable of which when excited emits at least one wavelength of second electromagnetic radiation. Stanley further teaches a photodiode detector (28) positioned adjacent to the radiation source (27) so as to be located on a same side of a same window of the respiratory flow component as the radiation source (27), positioned so as to be oriented toward the a same area the exterior surface of the respiratory flow component (24). Applicants further recite "an configured to sense a second electromagnetic radiation emitted by the luminescable composition and to produce a signal indicative of an intensity of the at least one wavelength emitted by the luminescable composition." Examiner would like to point out that applicants have not positively recited "a second electromagnetic radiation" since the recitation is recited in an intended use limitation. Intended use limitation in apparatus claims are of no patentable significance and merely requires the prior art capable of performing the intended use. The detector of Stanley teaches a detector (28) capable and configured to sense a second electromagnetic radiation. Stanley further teaches signal processor (23) and a luminescent oxygen sensor film (25). In operation, the sensor film is illuminated by the light source so as to excite fluorescent emission. The fluorescence is quenched quantitatively by oxygen present in the tube (14), and is measured by the detector (28).

The transducer of Stanley et al differs from the claimed invention in that it fails to specify that it is removably securable to the breathing tube only in a correct orientation.

Knodle et al disclose a similar optical sensor transducer for measuring carbon dioxide in a breathing tube. Knodle et al specifically disclose the transducer as being removably securable to breathing tubes (column 11, lines 34-45). It would have been obvious to one of ordinary skill in the art to removably secure the transducer of Stanley et al to an associated breathing in order to facilitate replacement thereof, as per the teaching of Knodle et al.

Regarding instant claim 2, Stanley et al provide a processor in the form of an amplifier and recorder in communication with the detector (28) (Figure 1). Regarding instant claim 3, see Stanley et al at column 3, lines 16-18). Regarding instant claim 5, see Figure 4 of Stanley et al recognizing a non-linear response over a broad range of oxygen concentrations. As such, it would have been obvious to one of ordinary skill to apply a different mathematical processing to lower range concentrations as compared with higher range concentrations. Stanley et al further teach excitation bands that encompass the visible spectrum (column 3, lines 12-15), and the particular wavelengths presently claimed.

Regarding claims 9-12, addressed in the rejection above, refer to intended use limitations. Applicants have not positively recited "a second electromagnetic radiation".

Regarding instant claims 17-19, it is noted that while Stanley et al teach measurement of oxygen in a breathing tube, Knodle et al teaches optical measurement of carbon dioxide in a breathing tube. Knodle et al teaches such detection utilizing an infrared source. Thus, it would have been obvious to one of ordinary skill in the art to

modify the transducer of Stanley et al to further include a second infrared light source to enable detection of both oxygen and carbon dioxide.

Regarding instant claims 20-23, see optical filters (16 and 17) disclosed by Stanley et al in Figure 2. Regarding instant claims 24-30, see Stanley et al at the paragraph bridging columns 4 and 5, recognizing sensor susceptibility to temperature variations. In view of such recognition, it would have been obvious to one of ordinary skill in the art to modify the device of Stanley et al to include a temperature regulation device including a heater component configured to contact a thermal capacitor of the respiratory flow component in order to maintain the sensing film at a desired, optimal operating temperature.

Regarding instant claims 31-34, it is noted that the presently claimed features are clearly provided by the structure depicted by Stanley et al in Figures 1 and 2.

Regarding instant claim 36, Stanley and Knodle both fail to explicitly teach that the detector (28) is substantially stable for a period of at least about 8 hours. However, Stanley does teach a detector and is clearly capable of being substantially stable for a period of at least about 8 hours. In view of such recognition, it would have been obvious to one of ordinary skill in the art to modify the device of Stanley providing the detector which is substantially stable for a period of at least about 8 hours in order to obtain an accurate measurement of varying concentrations of oxygen in the gas stream.

Regarding instant claim 37, Stanley and Knodle both fail to explicitly teach the detector has a stability of about  $\pm 2$  torr over eight hours at an atmospheric oxygen concentration. The detector of Stanley is capable of having a stability of about  $\pm 2$  torr



over eight hours at an atmospheric oxygen concentration. In view of such recognition, it would have been obvious to one of ordinary skill in the art to modify the device of Stanley providing a detector that has stability of about  $\pm 2$  torr over eight hours at an atmospheric oxygen concentration in order to obtain an accurate measurement of varying concentrations of oxygen in the gas stream.

6. **Claims 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Yafuso et al ('172).

Refer above for the teachings of Stanley and Knodle.

The transducer of Stanley et al further differs in that it fails to provide a beam divider and reference detector.

Yafuso et al teach teaches a beam divider (31) and a reference detector (33) of an optical detector for the purpose of accommodating variations in the excitation light. It would have been obvious to one of ordinary skill in the art to so modify the transducer to include a beam divider and a reference detector of Stanley et al in order to attain accurate measurements of oxygen concentrations. (See Col. 1, Lines 20-28)

7. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Hauenstein et al ('727).

Refer above for the teachings of Stanley and Knodle.

Stanley and Knodle fail to teach the radiation source is configured to emit electromagnetic radiation in a pulsed manner.

Hauenstein et al disclose an optical sensor for determination of oxygen through fluorescence quenching. Hauenstein et al further teach that a signal to noise ratio is enhanced by use of a pulsed excitation signal. It would have been obvious to one of ordinary skill in the art to so modify the transducer of Stanley et al in order to attain the known benefits thereof, as per the teaching of Hauenstein et al.

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure as background information related to applicant's field of endeavor.

9. **Claim 38** is rejected under 35 U.S.C. 103(a) as being unpatentable over Stanley et al in view of Knodle et al, as applied to claim 1, and further in view of Alcala et al.

Refer above for the teachings of Stanley and Knodle.

The transducer of Stanley et al further differs in that it fails to provide a signal processor that receives the signal from the detector and outputs a modified signal with a phase angle corresponding to a decay time of an excited luminescent composition of the respiratory flow component. Alcala et al teaches the decay times characteristics of a response signals. It would have been obvious to one of ordinary skill in the art to so modify the transducer of Stanley et al in order to further obtain lifetimes of the luminescent composition.

### ***Response to Arguments***

10. Applicant's arguments filed February 15, 2010 have been fully considered but they are not persuasive. Applicants argue that Stanley does not teach "a replaceable

luminescable element". As stated in the above rejection, it is the examiner's position that inherently any structure element is "replaceable". Refer to rejection above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI NAGPAUL whose telephone number is (571)272-1273. The examiner can normally be reached on Monday thru Friday (10:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jyoti Nagpaul/  
Primary Examiner, Art Unit 1797